Iowa Department of Public Health

Office of Medical Cannabidiol

Request for Proposals
to License Medical Cannabidiol Manufacturers

REQUEST FOR PROPOSAL #58821019

Initial License Effective Period:
November 20, 2020 - November 30, 2021

NOTICE: This RFP does not include any funding award

RFP Table of Contents

SECTION 1 – GENERAL AND ADMINISTRATIVE ISSUES

1.01 Purpose and Overview

The Medical Cannabidiol Act (2017 Iowa Acts House File 524), enacted on May 12, 2017, directed the Iowa Department of Public Health ("Department") to implement and administer The Medical Cannabidiol Act (Iowa Code chapter 124E as amended by HF2589, and with proposed rules related to HF2589 at ARC 5082c). This Act authorizes the Department to license up to two medical cannabidiol manufacturers in Iowa.

The purpose of this Request for Proposals (RFP) #58821019 is to solicit applications that will enable the Department to select and license the most qualified applicant as the second medical cannabidiol manufacturer to manufacture and to cultivate, extract, formulate and manufacture products, package, transport, and supply medical cannabidiol in the State of Iowa. Thereafter, the Department intends to renew the manufacturer licenses each year by December 1, in accordance with applicable administrative rules, unless a manufacturer relinquishes a license, there is a change in state law, or the license is revoked pursuant to Iowa Code chapter 124E or applicable administrative rules.

Applicants interested in obtaining a license to manufacture medical cannabidiol in Iowa must submit an application in response to this RFP. The Department expects an application to contain sufficient information to allow a thorough understanding of the applicant's ability to meet the requirements of the RFP and to operate as a medical cannabidiol manufacturer in accordance with Iowa law and administrative rules. Refer to Section 2 for additional details about licensure requirements and the manufacturing of medical cannabidiol in Iowa.

For purposes of this RFP, an Applicant is defined as the business entity applying to hold a manufacturing license. An individual with any ownership or financial stake, to include but not limited to employee, investor, owner, officer, director, would be considered a part of the business organization and thus the applicant.

1.02 Applicant & Application Eligibility Requirements

Current holders of a manufacturing license in Iowa are not eligible to apply.

Applicants for this RFP must meet each of the following eligibility requirements to be considered.

A. **Registered to do Business in Iowa:** Applicants must be registered to do business in Iowa through the Iowa Secretary of State's office. If not already registered, the applicant must minimally have started the registration process.
   - ➔ Evidence required with application:
     - ◆ Registered businesses: A file stamped copy of the organization's articles of incorporation or certificate of organization would be sufficient as evidence of submission of required materials.

- Non-registered businesses: If an applicant is not registered to do business in Iowa at the time of application, the applicant must provide evidence of submission of required materials to be registered to do business in the state of Iowa with the application.

B. **Obtain Local Zoning Authority:** Applicants must provide a completed Proper Zoning Form (refer to section 3), providing proof of approval from the municipality of their proposed manufacturing facility location. Applicants who do not submit a completed Proper Zoning form with their application by submission date will be rejected.

C. **Business Entity Ownership Disclosure:** All owners with an equal to or greater than 5% equity stake in the business entity must be disclosed; and no owner may have a history of a conviction of a disqualifying felony offense (refer to section 1.02 D). An owner is defined as any person who owns any share of the manufacturing business.

D. **Background Investigation and National Criminal History Background Check Fees:** To be eligible for a license, all owners of cannabidiol manufacturer business entities must submit information and pass/clear a Class A background investigation and a national criminal history background check conducted by the Iowa Department of Public Safety. A medical cannabidiol manufacturer owner shall not have been convicted of a disqualifying felony offense as defined in Iowa Code section 124E.2. A disqualifying felony offense means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C §802(6). To be eligible for a license, all owners of applicant manufacturer business entities must submit information and pass/clear a background investigation and a national criminal history background check conducted by the Iowa Department of Public Safety. Owners or partners who are added after an application is submitted or after a license is issued must also pass/clear a background investigation and a national criminal history background check conducted by the Iowa Department of Public Safety to be added to a license.

If any owner of the applicant manufacturer has been convicted of a disqualifying felony offense, that manufacturer should not apply. If a violation is discovered, any pending or issued medical cannabidiol manufacturer license will be revoked and the applicant will have forfeited any fees submitted to the Department or to the Department of Public Safety.

Payment in the form of a cashier check written to the Department of Public Safety in the amount of $10,000 per owner must be submitted immediately following the posting of the notice of intent to award the manufacturer license. These funds will serve as a deposit for the costs associated with the background investigation and national criminal history background check on each owner. Background investigation and national criminal history background check costs shall be deducted from the funds deposited. If background investigation and national criminal history background check fees exceed the funds deposited, the applicant shall submit additional funds as

required by the Department of Public Safety. If the background investigation and national criminal history background check fees are less than the funds deposited, the Department of Public Safety may refund or retain the fees as mutually agreed with the manufacturer.

Instructions for the background investigations and national criminal history background checks that are required as part of the application will be sent to the successful applicant following the award of a manufacturer license. The applicant shall cause all waivers and fingerprinting to be executed by appropriate persons to effectuate the background investigations and checks. As a condition of application to this RFP, applicants shall submit to the Department immediately upon request, the following items:

- Completed background investigation and national criminal history background check forms for each owner
- Fingerprint cards for each owner
- Releases necessary to conduct the background investigation and national criminal history background check

E. **Submit a Letter of Intent to Apply:** Applicants must submit their intent to apply for a manufacturing license by the letter of intent deadline to be eligible to apply and submit a final application for license. Refer to section 1.04 below for additional details and schedule.

F. **Provide the Application Fee:** An applicant must submit the application fee by the deadline provided. Refer to section 1.04 below for additional details and guidance. Failure to submit the application fee for receipt by the Department by the deadline will result in a submitted application to be rejected during technical review (refer to Section 4).

1.03 Service Delivery Area/Supply

An applicant may select the manufacturing location within Iowa, and must identify the physical location in their application. An applicant must receive local zoning authority via the Proper zoning form for the location of their choosing.

1.04 Application Fees

As required by the Medical Cannabidiol Act (Iowa Code chapter 124E), applicants are required to pay a nonrefundable application fee of seven thousand five hundred dollars ($7,500) to the Department for the medical cannabidiol manufacturer licensure. Refer to section 1.05 D for details and instructions regarding this payment. Applicants that fail to submit application fees in accordance with section 1.05 D for each application submitted will have their corresponding applications rejected (refer to section 4).

1.05 Schedule of Important Dates (All times and dates listed are local Iowa time.)

The following dates are set forth for informational purposes. The Department reserves the right to change them.

EVENT	DATE
RFP Issued	September 8, 2020
Intent to Apply Letter Due by:	**October 9, 2020 by 4:00 p.m.**
Written Questions and Responses	
Round 1 Questions Due: Responses Posted By:	October 2, 2020 October 5, 2020
Round 2 Questions Due: Responses Posted By:	October 9, 2020 October 12, 2020
Round 3 Questions Due: Responses Posted By:	October 16, 2020 October 19, 2020
Applications & Application Fee Due	**October 23, 2020 by 4:00 p.m. local Iowa time**
Post Notice of Intent to License Award Status	November 20, 2020

A. **RFP Issued**
The Department will post the RFP on the Department website under Funding Opportunities at http://idph.iowa.gov/ on the date referenced in the Event Date table above. The RFP will remain posted through the Applications Due date.

B. **Intent to Apply Letters Due: Letters of Intent must be received by 4:00 p.m. (local Iowa time) October 9, 2020.**

Failure to submit an Intent to Apply Letter(by the deadline) will result in rejection of the application for which no Intent to Apply Letter was submitted.

Intent to Apply Letters must be received by Melana Hammond via email to Melana.Hammond@idph.iowa.gov by October 9, 2020, by 4:00 p.m. (local time), with the subject line "Medical Cannabidiol Manufacturer RFP Intent to Apply." This requirement is a mandatory requirement and will **not** be subject to waiver as a minor deficiency**.**

The Intent to Apply Letter must contain the following information:

1. The name of the business for which the application is being submitted.
2. The name(s) of the owner(s) of the business for which the application is being submitted.
3. The name, telephone number, and email address of the business representative who will act as point of contact for RFP purposes.

Intent to Apply Letters received by the Department after the stated due date and

time will be rejected. If an Intent to Apply Letter is not received in accordance with the timeline above, the application will not be accepted and considered.

C. **Written Questions and Responses**
Written questions related to the RFP must be submitted via electronic mail to Melana.Hammond@idph.iowa.gov no later than the due dates specified for each round in the Event Date table above. If the question or comment pertains to a specific section of the RFP, the section and page must be referenced. Oral questions will not be accepted.

The Department will prepare written responses to all pertinent, timely and properly submitted questions according to the Event Date table above. Responses will be posted on the Department website under Funding Opportunities as a PDF document. The Department's written responses will be considered part of the RFP.

It is the responsibility of the applicant to review written questions and responses to this RFP as posted on the Department website under Funding Opportunities at http://idph.iowa.gov/.

D. **Application Submission and Application Fee Due: Final Applications must be received by 4:00 p.m. (local Iowa time) October 23, 2020.** This requirement is a mandatory requirement and will **not** be subject to waiver as a minor deficiency.

All application information must be provided in the order and format established in the RFP, and clearly labeled with the RFP sections and subparts. Refer to Section 3.01 for Application Format. A complete application package must include:

1. One (1) original and two (2) paper copies of the application, inclusive of all required information, with each application single-sided and securely bound.
2. One CD containing a complete electronic version of the entire paper/original application. The electronic version must be inclusive of all required information, in a searchable PDF file format. All documents listed in the CD must *match* the original and copies submitted.
3. As applicable: One CD containing a redacted version of the application (if any) submitted in compliance with section 1.24 and 1.25 of this RFP.
4. One cashier check made out to the Iowa Department of Public Health for $7,500 as payment of the non-refundable application fee.

Applications received by the Department after the stated due date and time will be rejected and not reviewed by the Department. Applicants will be notified of the rejection after the due date.

Application package must be hand delivered or mailed* to the Department to the attention of:

Melana Hammond, Contract Compliance Officer
Iowa Department of Public Health
Lucas State Office Building - 6th Floor
321 East Twelfth Street
Des Moines, Iowa 50319-0075

*Applicants who choose to mail applications must allow ample mail delivery time to ensure timely receipt of their applications by the Department. Postmarking by the due date will **not** substitute for actual receipt of the application by the Department. It is the applicant's responsibility to ensure that the application is date and time stamped as "Received" by the Department prior to the deadline.

Electronic mail and faxed copies of the application **will not** be accepted.

Any information submitted separately from the application will not be considered in the review process.

E. Release of Names of Applicants: **November 2, 2020**

The names of all applicants that submitted applications by the deadline shall be released to all who have requested such notification via email from Melana Hammond at melana.hammond@idph.iowa.gov. The announcement of applicants who timely submitted an application does not mean that an individual application has been deemed technically compliant or accepted for evaluation.

Following the due date of the Intent to Apply Letter, the Department may release the number of completed intents to apply.

F. Notice of License Award Status

A Notice of License Award Status will be posted for 10 business days on the Department Web page http://idph.iowa.gov/ select 'Notice of Intent to Award' link under 'Funding Opportunities' by 4:30 pm on the date specified in the Schedule of Events table above. Applicants are solely responsible for reviewing the Notice of License Award to determine their award status.

The notice will indicate the License Award Status for each application accepted for Application review (refer to section 4), in accordance with the following definitions:

1. **License-offered:** This license status means the application for a specific manufacturing location has met the minimum score and the Department will offer a license for that specific location. The applicant must comply with any requested negotiations to the submitted application and accept the license within 48 hours from notice from the Department.

2. **License-eligible:** This license status means the application for a specific manufacturing location has met the minimum score, but the Department does not anticipate providing a license unless another applicant does not accept a license, a license is revoked, or if the statute changes to allow additional licenses prior to

December 1, 2020. If the Department, at its sole discretion, offers a license to a license-eligible applicant prior to December 1, 2020, the applicant must comply with any requested negotiations to the submitted application and accept the license within 48 hours from notice from the Department.

3. **License Non-eligible:** This license status means the application for a specific manufacturing location has not met the minimum score to be considered for a license under this RFP process.

1.06 Inquiries

During the period following release of this RFP and during the period of evaluation, applicants should contact only Melana Hammond in the manner provided for in Section 1.05(C). Unauthorized contact regarding this RFP with other state employees or officials may result in disqualification. In no case shall verbal communications override written communications. Only written communications are binding on the Department.

The Department assumes no responsibility for representations made by its officers or employees unless such representations are specifically incorporated into the RFP.

Any verbal information provided by the applicant shall not be considered part of its application.

1.07 Amendments to the RFP

The Department reserves the right to amend the RFP at any time. In the event the Department decides to amend, add to, or delete any part of this RFP, a written amendment will be posted on the Department website under Funding Opportunities. The applicant is advised to check the Department website periodically for amendments to this RFP. In the event an amendment occurs after the Funding Opportunity is closed and removed from the website, the Department will email the written amendment to the individual identified as the point of contact in the submitted intent to apply.

1.08 Open Competition

No attempt shall be made by the applicant to induce any other person or firm to submit or not to submit an application for the purpose of restricting competition.

1.09 Withdrawal of Applications

Applications may be withdrawn, modified and resubmitted at any time prior to the stated due date and time for the receipt of applications. An applicant desiring to withdraw an application shall submit notification via email to Melana.Hammond@idph.iowa.gov.

1.10 Acceptance of Terms and Conditions

A. An applicant's submission of an application constitutes acceptance of the terms, conditions, criteria and requirements set forth in the RFP and operates as a waiver of any and all objections to the contents of the RFP. By submitting an application, an applicant agrees that it will not bring any claim or have any cause of action against the Department or the State of Iowa based on the terms or conditions of the RFP or the award process.

B. The Department reserves the right to accept or reject any exception taken by an applicant to the terms and conditions of this RFP. Should the successful applicant take exception to the terms and conditions required by the Department, the successful applicant's exceptions may be rejected and the Department may elect to terminate award to that applicant.

1.11 Costs of Application Preparation

All costs of preparing the application are the sole responsibility of the applicant. The Department is not responsible for any costs incurred by the applicant which are related to the preparation or submission of the application or any other activities undertaken by the applicant related in any way to this RFP.

1.12 Multiple Applications

An applicant may submit only one application. For purposes of this RFP, an Applicant is defined as the business entity applying to hold a manufacturing license. An individual with any ownership or financial stake, to include but not limited to: employee, investor, owner, officer, director, would be considered a part of the business organization and thus the applicant.

An applicant may not be party to another application as an owner, investor, director, officer, or employee.

1.13 Oral Presentation

Applicants may be requested to make an oral presentation of the application. The determination of need for presentations and the location, order, and schedule of the presentations is at the sole discretion of the Department. If an oral presentation is required, applicants may clarify or elaborate on their applications, but may in no way change their original application.

1.14 Rejection of Applications/Cancellation of the RFP

A. The Department reserves the right to reject, in whole or in part, any or all applications, to advertise for new applications, to abandon the need for such services, and to cancel this RFP if it is in the best interests of the Department.

B. Any application will be rejected outright and not evaluated for any of the following reasons:

1. The applicant fails to submit the Intent to Apply Letter by the date and time stated in Section 1.05.
2. The applicant fails to submit the application by the date and time stated in Section 1.05.
3. The applicant is not an eligible applicant as defined in Section 1.02.
4. An applicant submits more than one application.
5. An application is submitted in a manner other than that specified in this RFP.
6. The applicant fails to receive local authorization for the proposed manufacturer location.
7. The applicant fails to submit the application fee.

C. Any application may be rejected outright and not evaluated for any of the following reasons:

1. The applicant fails to include required information or fails to include sufficient information to determine whether an RFP requirement has been satisfied.
2. The applicant fails to follow the application instructions or presents information requested by this RFP in a manner inconsistent with the instructions of the RFP.
3. The applicant provides misleading or inaccurate answers.
4. The applicant states that a mandatory requirement cannot be satisfied.
5. The applicant's response materially changes a mandatory requirement.
6. The applicant's response indicates inability to comply with a mandatory requirement of the Medical Cannabidiol Act, Iowa Code chapter 124E, 641 Iowa Administrative Code 154, or proposed administrative rules.
7. The applicant's response limits the right of the Department.
8. The applicant fails to respond to the Department's request for information, documents, or references.
9. The applicant fails to include any signature, certification, authorization, or stipulation requested by this RFP.
10. The applicant initiates unauthorized contact regarding the RFP with a state employee or official.

1.15 Restrictions on Gifts and Activities

Iowa Code chapter 68B contains laws which restrict gifts which may be given to or received by state employees and requires certain individuals to disclose information concerning their activities with state government. Applicants are responsible for determining the applicability of this chapter to their activities and for complying with these requirements.

In addition, Iowa Code chapter 722 provides that it is a felony offense to bribe a public official.

1.16 Reference Checks

The Department reserves the right to contact any reference to assist in the evaluation of the application, to verify information contained in the application, and to discuss the applicant's qualifications.

1.17 Criminal Background Checks

The Department reserves the right to conduct background investigations and national criminal history background checks of the applicant, its officers, directors, managerial and supervisory personnel, clerical or support personnel, and contractors retained by the applicant.

The Department of Public Safety, on behalf of the Department, will conduct background investigations and national criminal history background checks of the applicant manufacturer business owner(s) and employees as described in Section 1.02 D and Section 2. The applicant is responsible for the costs associated with the background investigations and national criminal history background checks as described in this RFP. Results of the background checks may be used in determining license awards.

1.18 Information from Other Sources

The Department reserves the right to obtain and consider information from other sources concerning an applicant, including the applicant's product or services, personnel, and contractors, and the applicant's capability and performance under other Department contracts, other state contracts, and contracts or licenses with other states or private entities. The Department may use any of this information in evaluating an applicant's application.

1.19 Verification of Application Contents

The Department reserves the right to verify the contents of an application submitted by an applicant. Misleading or inaccurate responses may result in rejection of the application pursuant to Section 1.14.

1.20 Litigation or Investigation Disclosure

The applicant shall disclose any pending or threatened litigation, administrative, or regulatory proceedings or similar matters which could affect the ability of the applicant to manufacture medical cannabidiol. Failure to disclose such matters at the time of application may result in rejection of the application or in revocation of any license. This is a continuing disclosure requirement. Any such matter commencing after submission of an application or award of a license must be disclosed within 30 days in a written statement to the Department.

1.21 Financial Accountability

The applicant shall maintain sufficient financial accountability and records. The applicant shall disclose each irregularity of accounts maintained by the applicant discovered by the applicant's accounting firm, the applicant, or any other third party. Failure to disclose such matters, including the circumstances and disposition of the irregularities, at the time of application within the Narrative Section: Business Organization, Ownership and Financial Structure (Refer to Section 3 of this RFP) may result in rejection of the application or in revocation of any license. This is a continuing disclosure requirement. Any such matter commencing after submission of an application must be disclosed within 30 days in a written statement to the Department.

1.22 RFP Application Clarification Process

The Department may request clarification from applicants for the purpose of resolving ambiguities or questioning information presented in the application. Clarifications may occur throughout the application evaluation process. Requests for clarification will be issued to the Applicant via email from an IDPH Service Contract Compliance Officer. Clarification responses shall be in writing in the format provided by the Department and shall address only the information requested. Responses shall be submitted to the Department within the time stipulated at the time of the request. An applicant will not be permitted to modify or amend its application if contacted by the Department for this reason.

1.23 Waivers and Variances

The Department reserves the right to waive or permit cure of non-material variances in the application's form and content providing such action is in the best interest of the Department. In the event the Department waives or permits cure of nonmaterial variances, such waiver or cure will not modify the RFP requirements or excuse the applicant from full compliance with RFP specifications or other legal requirements if the applicant is awarded a license. The determination of materiality is in the sole discretion of the Department.

1.24 Disposition of Applications

All application submissions become the property of the Department.

If the Department awards a license to an applicant, the contents of all applications will be in the public domain at the conclusion of the selection process and will be open to inspection by interested parties subject to exceptions provided in Iowa Code chapter 22 or other provision of law and as stated in Section 1.25 of this RFP.

1.25 Public Records and Requests for Confidential Treatment of Application Information

Pursuant to Iowa Code section 124E.6(1)"b", information submitted during the application process shall be confidential until the licensure process is completed unless otherwise

protected from disclosure under state or federal law.

The Department's release of public records is governed by Iowa Code chapter 22. Applicants are encouraged to familiarize themselves with Chapter 22 before submitting an application in response to this RFP.

The Department will copy and produce public records upon request as required to comply with Chapter 22 and will treat all information submitted by an applicant as non-confidential records unless applicant requests specific parts of the application be treated as confidential at the time of the submission as set forth herein AND the information is confidential under Iowa or other applicable law.

All information submitted by an applicant will be treated as public information following the conclusion of the selection process unless the applicant properly requests that information be treated as confidential at the time the application is submitted.

Failure of the Applicant to request information be treated as confidential as specified herein shall relieve Department personnel from any responsibility for maintaining the information in confidence. Applicants may not request confidential treatment with respect to pricing or budget information and transmittal letters. An applicant's request for confidentiality that does not comply with this section or an applicant's request for confidentiality on information or material that cannot be held in confidence as set forth herein are grounds for rejecting an application as non-responsive.

A. Confidential Treatment of Information is Requested by the Applicant:
   An applicant requesting confidential treatment of information contained in its application shall be required to submit two versions of its application (one complete version (containing confidential information) and one redacted version (with confidential information excised) and complete and submit Form 22 for each version; as outlined herein:

   1. Complete and Submit Form 22 for each version:

      <u>APPLICANT NOTE: SUBMISSION OF THIS FORM 22 IS REQUIRED ONLY IF REQUESTING CONFIDENTIAL TREATMENT OF APPLICATION INFORMATION.</u>

      In order to request information contained in an application to be treated as confidential, the applicant must complete and submit Form 22 with both versions. Failure of the applicant to accurately and fully complete Form 22 with the application submission may result in the application to be considered non-responsive and not evaluated. The Form 22 is available to download from a link located in Section 6 - Links. An applicant must download Form 22 from a link within this form, complete it, and include it with both versions of the application (original and redacted).

Form 22 will not be considered fully complete unless, for each confidentiality request, the applicant: (1) enumerates the specific grounds in Iowa Code chapter 22 or other applicable law that supports treatment of the material as confidential, (2) justifies why the material should be maintained in confidence, (3) explains why disclosure of the material would not be in the best interest of the public, and (4) sets forth the name, address, telephone, and e-mail for the person authorized by applicant to respond to inquiries by the Department concerning the confidential status of such material. Requests to maintain an entire application as confidential will be rejected as non-responsive.

2. An applicant that submits an application containing confidential information must submit two versions of its application (one complete, non-redacted version and one redacted version of the application) for this RFP. Completed Form 22 shall be included in both versions.

   One version of the application must be completed and submitted in its entirety, containing the confidential information. This is the application that will be reviewed.

   The applicant must submit one version of the application labeled “Redacted Copy” from which the confidential information had been excised. The applicant must then revise each form within the copied/redacted version removing the confidential information and inserting the word ‘redacted’. The confidential material must be excised from the redacted version in such a way as to allow the public to determine the general nature of the material removed and to retain as much of the application as possible.

   Both versions of the application must be submitted by the applicant by the due date and time outlined in Section 1.05 (D).

B. Public Requests:
In the event the Department receives a public request for application information marked confidential, written notice shall be given to the applicant seventy-two (72) hours prior to the release of the information to allow the applicant to seek injunctive relief pursuant to Iowa Code Section 22.8. The information marked confidential shall be treated as confidential information to the extent such information is determined confidential under Iowa Code Chapter 22 or other provisions of law by a court of competent jurisdiction. If the Department receives a request for information that applicant has marked as confidential and if a judicial or administrative proceeding is initiated to compel the release of such material, applicant shall, at its sole expense, appear in such action and defend its request for confidentiality. If the applicant fails to do so, the Department may release the information or material with or without providing advance notice to the applicant and with or without affording the applicant the opportunity to obtain an order restraining its release from a court possessing competent jurisdiction.

Additionally, if applicant fails to comply with the request process set forth herein, if

applicant's request for confidentiality is unreasonable, or if applicant rescinds its request for confidential treatment in writing, the Department may release such information or material with or without providing advance notice to applicant and with or without affording applicant the opportunity to obtain an order restraining its release from a court possessing competent jurisdiction.

The applicant's failure to request confidential treatment of material pursuant to this section and the relevant law will be deemed by the Department as a waiver of any right to confidentiality which the applicant may have had.

1.26 Copyrights

By submitting an application, the applicant agrees that the Department may release the application for the purpose of facilitating the evaluation of the application or to respond to requests for public records. By submitting the application, the applicant consents to such release and warrants and represents that such release will not violate the rights of any third party. The Department shall have the right to use ideas or adaptations of ideas that are presented in the applications. In the event the applicant copyrights its application, the Department may reject the application as noncompliant.

1.27 Appeal of Rejection Decision

The applicant's receipt of a rejection letter constitutes receipt of notification of the adverse decision per 641 Iowa Administrative Code chapter 176.8(1). Applicants may appeal the adverse decision only for a timely submitted application. The appeal shall be submitted in writing within ten business days of receipt of notification of the adverse decision. Appeals shall be submitted in writing, return receipt requested, to Melana Hammond, Contract Compliance Officer, Division of Administration and Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Appeals must clearly and fully identify all issues being contested and demonstrate what procedures in the RFP were not followed. In the event of an appeal, the Department will continue working with the successful applicant(s) pending the outcome of the appeal.

1.28 Appeal of License Award Decision

The posting of the Notice of License Award Status on the Department website constitutes receipt of notification of the adverse decision per 641 Iowa Administrative Code Chapter 176.8(1). Applicants may appeal the adverse decision only for a timely submitted application. The appeal shall be submitted in writing within ten business days of receipt of notification of the adverse decision. Appeals shall be submitted in writing, return receipt requested, to Melana Hammond, Contract Compliance Officer, Division of Administration and Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Appeals must clearly and fully identify all issues being contested and demonstrate what procedures in the RFP were not followed. In the event of an appeal, the Department will continue working with the successful applicant(s) pending the outcome of the appeal.

1.29 Construction of RFP

This RFP shall be construed in light of pertinent legal requirements and the laws of the State of Iowa. Changes in applicable statutes and rules may affect the award process. Applicants are responsible for ascertaining the relevant legal requirements. Any and all litigation or actions commenced in connection with this RFP shall be brought in the appropriate Iowa forum.

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SECTION 2 – DESCRIPTION OF MINIMUM REQUIREMENTS FOR LICENSE

This section of the RFP describes minimum expectations of the medical cannabidiol manufacturer. Section 3 of this RFP details the requirements of the application content.

The Iowa Medical Cannabidiol Act requires the Department to select and license up to two medical cannabidiol manufacturers in Iowa. Iowa currently has one licensed medical cannabidiol manufacturer, therefore one additional medical cannabidiol manufacturer may be licensed by the Department through this RFP.

The successful Applicant to this RFP is responsible for compliance with the Medical Cannabidiol Act, Iowa Code chapter 124E, as amended by HF2589, as well as all proposed and final administrative rules. The Act, the current administrative rules, and the proposed rules can be found at the links included in this RFP, also refer to section 6 - Links.

The Medical Cannabidiol Act allows a qualifying patient or primary caregiver who is registered with the Department to possess medical cannabidiol for the treatment of the patient's debilitating medical condition(s). (The Department's administrative rules pertaining to patients, primary caregivers, and debilitating medical conditions can be found at 641 IAC 154 with proposed rules related to HF2589 at ARC 5082c).

Medical cannabidiol must be manufactured by a manufacturer licensed by the Department and registered patients and caregivers must purchase it from a dispensary licensed by the Department. (The Department's implemented administrative rules pertaining to manufacturers and dispensaries can be found at 641 IAC 154 with proposed rules related to HF 2589 at ARC 5082c.)

The selected manufacturer(s) will be expected to manufacture and to cultivate, extract, formulate and manufacture products, package, transport, and supply medical cannabidiol within this state consistent with the provisions of the Medical Cannabidiol Act, as well as the implemented and proposed administrative rules.

License Effective Dates and Annual Fees

As a condition for licensure, a medical cannabidiol manufacturer must agree to begin supplying medical cannabidiol to medical cannabidiol dispensaries in this state no later than July 1, 2021, and must provide an operational timeline in a narrative response in Section 3 exhibiting their ability to do so.

The Department expects the initial license will be valid from November 20, 2020, through November 30, 2021.

The Department intends to renew the license annually unless a manufacturer relinquishes a license, there is a change in state law prohibiting the Department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or administrative rules.

Iowa Code section 124E.10 requires the Department to collect annual fees in an amount sufficient to regulate the medical cannabidiol manufacturers and dispensaries, to cover the cost of salaries for two agents of the Division of Criminal Investigation of the Department of Public Safety, and for other expenses that are necessary to administer chapter 124E, including the costs of information technology systems. At this time, annual fees for Year 1 are payable by December 1, 2020, and are anticipated to be $80,000. This estimate is subject to revision based on changes in the law or any other factors that may impact the program budget.

License Effective Area

A medical cannabidiol manufacturer license is effective for the entire state of Iowa.

Employee Background Checks and Fees

A medical cannabidiol manufacturer shall not employ a person who is under eighteen years of age or who has been convicted of a disqualifying felony offense. An employee of a medical cannabidiol manufacturer shall be subject to a background investigation and national criminal history background check conducted by the Division of Criminal Investigation of the Department of Public Safety.

Upon notice of license award, the licensed manufacturer will pay a deposit of $200 per employee to the Department of Public Safety for background investigations and national criminal history background checks for every employee and every prospective employee of the manufacturer. Background investigation and national criminal history background check costs shall be deducted from the funds deposited. If the background investigation and national criminal history background check fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the Department of Public Safety. If the background investigation and national criminal history background check fees are less than the funds deposited, the Department of Public Safety may refund or retain the fees as mutually agreed with the manufacturer.

Manufacturing Minimum Requirements

The successful Applicant will be responsible for compliance with the implemented administrative rules at 641 IAC 154 and the proposed rules related to HF2589 at ARC5082C.

Inspections and Product Standards

A medical cannabidiol manufacturer is subject to reasonable inspection by the Department.

The licensed medical cannabidiol manufacturer shall be required to contract with the State Hygienic Laboratory at the University of Iowa in Iowa City or an independent medical cannabidiol testing laboratory to perform testing of the medical cannabidiol produced by the manufacturer as to the content, contamination and consistency of the product. The

Department shall require that the laboratory report testing results to the manufacturer in a manner described in the implemented administrative rules 641 IAC 154.

The cost of all laboratory testing shall be paid by the medical cannabidiol manufacturer.

The Department's Secure Sales and Inventory Tracking System

The Department maintains a Secure Sales and Inventory Tracking System for the monitoring and tracking of *Cannabis* plant material inventory, manufacturing and production processes, and medical cannabidiol product inventory. The system is designed to alert the Department of potential diversion (tracking any inventory lost at any point from seed to sale) and to ensure public safety (tracking product sold to patients back to the plant level). The Department has contracted with Flok Consulting to develop and manage the Department's secure sales and inventory tracking system.

A manufacturer shall select a software vendor to enter data using an application program interface into the Department's system. Any system used by a manufacturer must be capable of integrating with the Department's system so that all required data can be sent to and maintained by the Department. A manufacturer shall be responsible for any costs to integrate its system with the Department's. The system will also generate all transport manifests between manufacturers, dispensaries, and laboratories.

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SECTION 3 – APPLICATION FORMAT AND CONTENT

This section of the RFP prescribes the format and content of the application and is designed to facilitate the submission of an application that is easy to understand, review, and evaluate. The applicant is solely responsible for including all information requested throughout this RFP in the submitted application. Failure to adhere to these requirements and application content may result in rejection of the application.

This RFP includes forms that the applicant must download and complete (from the Department website under Funding Opportunities), and provides direction for the applicant to obtain other documents or write narrative responses.

3.01 Technical Requirements

A. Applications must be typewritten and follow the format delineated herein. All application information must be provided in the order and format established in the RFP, and clearly labeled with the RFP sections and subparts.

Aspect	Requirement
Length	Page limitations apply only to the narrative portions of the RFP, refer to Section 3.02. Narrative will be limited to 200 pages. This limitation excludes Mandatory Certification Forms, Operating Procedures, Floor Plans, and any other supporting document required or suggested.
Font and font size	Narrative portions must be typed using a 12-point font, preferably in Times New Roman. Applications must include required forms. Tables, operating documents, figures or maps may be submitted in original format. No portion of the application may be hand written except for the areas on documents that require signatures. Handwritten applications will not be accepted.
Margins	Narrative must be a minimum of one inch on all sides.
Spacing	Application must be single-sided. Narrative should be 1.5 spacing, unless on a required form provided by the Department. Tables, operating documents, figures or maps may be submitted in original format.
Header or Footer and Pagination	Preferred: Insert a header or footer that identifies the applicant name, page number. All pages must be sequentially numbered (1, 2, 3…), preferably at the top right corner of each page. Pagination of the Medical Cannabidiol Manufacturer Application Certification and Conditions Form, maps, charts, budget pages, tables, and appendices or attachments is required; and beginning with the Medical Cannabidiol Manufacturer Application Certification and Conditions Form as page number one.
Copies	Submit one (1) original application (hard copy) and two (2) copies (hard copy) of the entire application.
CD/Electronic Copy	One CD must be submitted with an electronic copy that contains the content of the entire application, inclusive of **all information** and in searchable PDF file format.

	And, if submitting a redacted version, a second CD must be submitted with an electronic copy of the redacted version (must be in compliance with section 1.24 and 1.25). All documents listed in the CD must *match* the original (hard copy) and copies submitted.
Mandatory Certification Forms	The forms listed in Section 3.02 Mandatory Certification Forms must be completed and signed as directed.
Binding	The original and each copy must be securely bound.

B. Promotional materials or items other than required by this RFP will not be considered during the review process.

C. Any information or materials submitted separately from the application will not be considered in the review process.

3.02 Application Content

A. Medical Cannabidiol Manufacturer Application Certification and Conditions Form

This form identifies the applicant business's legal name and contact information. Applicants must download this form which is posted separately and complete the form following these instructions:

- Applicant – Provide the **legal name** of the applicant entity. This must be the entity associated with the Federal Identification (ID) number assigned by the Internal Revenue Service (IRS). If the entity operates under another name as a "d/b/a" (doing business as), please include that in the legal name.
- IRS # – Provide the applicant's **last four digits** of the federal identification number.
- Conditions/Signature – The person authorized to legally obligate the applicant must sign and date in non-black ink to certify that the applicant is in agreement with the conditions listed.

This form provides for the certification and assurance of the Applicant's intent and commitment to provide the services included in the application pursuant to Iowa Code chapter 124E and 641 Iowa Administrative Code (IAC) chapter 154 if a license is issued. Optional portions of this form include a request for confidentiality in compliance with section 1.25 of this RFP and inclusion of transmittal letters and other applicable communications.

The Certification and Conditions Form is required to be completed, signed, and dated by the Executive Director (ED) or Chief Executive Officer (CEO) of the applicant.

B. Mandatory Certification Forms

Mandatory forms are required. An application that does not include the mandatory forms listed below will be rejected during the technical review and will not be reviewed.

Applicants must download each form, print, sign and include it with the application. Refer to the forms posted separately, but with this RFP, in section 5.

The Mandatory Certification Forms include:

1. Statutory Requirements Certification Form
2. Licensing Regulatory Authority Release Form
3. Proper Zoning Form
4. Owner Certification Form

The content of mandatory forms will be considered in evaluating (scoring) applications.

1. **Statutory Requirements Certification Form:** This form certifies that the applicant is knowledgeable of and will comply with all statutory requirements outlined in this RFP #58821019. The applicant attests that he/she is authorized to provide such information and to bind the applicant. For any statement for which the answer is no, the applicant must provide a brief explanation.

2. **Licensing/Regulatory Authority Release Form:** This form certifies that the applicant is providing the Department with all requested regulatory agency information related to all past and current cannabis licenses **for every owner with greater than or equal to 5% ownership**, and authorizes the Department to contact the listed agencies for the purposes of RFP #58821019.

- For all applicant owners, any license, authorization or registration number of previous or current interest in cannabis business entities, the applicant must provide:
    1. License, authorization, or registration number for all past and current licenses.
    2. State agency or authority contact name, phone, and email.
    3. Indicate whether the license, authorization or registration has received any denial, suspension, revocation, notices of noncompliance, or other sanction of the application, license, or authorization of a cannabis business in any jurisdiction, indicate each license and provide:
        a. A copy of documentation so indicating; or
        b. A statement that the applicant was so licensed, authorized, or registered and was never sanctioned.

IDPH reserves the right to accept or reject any exception taken by an applicant to the terms and conditions listed. The person completing the form attests that he/she is authorized to provide such information and to bind the applicant manufacturer.

3. **Proper Zoning Form:** This form provides proof of approval from the municipality of the applicant's proposed manufacturing facility location and certifies that the applicant is providing the Department with requested zoning information via notarized verification of zoning information for the purposes of RFP #58821019. The person completing the form attests that he/she is authorized to provide such information and to bind the applicant manufacturer. For any statement for which the answer is no, the applicant must provide a brief explanation.

4. **Owner Certification Form(s):** This form certifies that each applicant manufacturer owner is providing the Department with requested business and professional information and acknowledges State and Federal law for the purposes of RFP #58821019. **A separate form must be completed per owner with 5% or greater ownership interest in the business entity.** By completing this form, each applicant manufacturer owner attests that he/she is authorized to provide such information and to bind the applicant manufacturer with his/her responses. For any statement for which the answer is 'no,' the applicant must provide a brief explanation.

3.03 Narrative Sections

The Department expects an application to fully address the contents of every narrative section and to contain sufficient information to allow a thorough understanding of the applicant's ability to meet the requirements of the RFP and to operate as a medical cannabidiol manufacturer, in accordance with Iowa laws and regulations. As outlined in Section 3.01 Technical Requirements, narrative responses are limited to a total of 200 pages. This page limit does not include Mandatory Certification Forms, Operating Procedures, Floor Plans, and any other document required or suggested.

The narrative sections listed below are required:

1. Business Organization, Ownership, and Financial Structure
2. Manufacturing Facility
3. Security Requirements
4. Personnel Background and Training
5. Cultivation
6. Extraction
7. Medical Cannabidiol Product Formulation & Manufacturing
8. Quality Assurance and Control
9. Packaging and Labeling
10. Transportation
11. Disposal
12. Record-Keeping Requirements
13. Supply and Inventory
14. Business Overview and Plan
15. Advertising and Marketing

16. Operating Documents

Applicants may be required to submit additional documents within each narrative section of the application, for example, a table of organization, operating documents, or other information to fully be responsive to each section. Applicants shall incorporate the necessary documents in the correct place in the application.

Narrative sections will be considered in evaluating applications.

1. Business Organization, Ownership, and Financial Structure

A. Contact Information: Provide general information about the applicant business entity including:
   1. Legal name of the eligible applicant
   1. Applicant legal address
   2. Applicant's last 4 digits of federal tax ID number
   3. Applicant's phone number
   4. The name of the Executive Director or CEO of the applicant organization. If the applicant is a board of health/board of supervisors, include the name of the board's authorized signatory.

B. Business Structure: Describe the applicant manufacturing business structure, for example, but not limited to, sole proprietorship, limited partnership, or C-corporation. Provide (as applicable):
   1. Articles of incorporation
   2. Articles of association
   3. Charter
   4. By-laws
   5. Partnership agreement
   6. Any agreements between any two or more members of the applicant manufacturer's business that relate in any manner to the assets, property or profit of the applicant or
   7. Any other comparable documents that set forth the legal structure of the applicant or relate to the organization, management, or control of the applicant.

C. Organizational Chart: Provide a current organizational chart, including the names of persons holding each position, to the extent such positions have been filled.

D. Resumes: Provide the resume of each person listed on the organizational chart setting out the individual's particular skills, education, experience or significant accomplishments that are relevant to the position.

E. Investors: Provide a list of owners, their ownership percentage and financial investment for all investors.
   1. Describe future financial investments and commitments per owner or investor and potential owners or investors.
      a. Provide the amount of future financial investment and the timeline the commitment is valid for.
      b. Each commitment should be accompanied by a letter certified by a Certified Public Accountant (CPA) verifying that the commitment by each owner (or potential owner) does not exceed 50% of their personal net worth. If such commitment exceeds 50% of an owner or potential

owner's personal net worth, indicate the percentage of that person's net worth that the commitment represents.

F. Compensation Agreements: Provide copies of all compensation agreements with investors, board members, directors, owners, officers, and other management. For purposes of this RFP, a compensation agreement includes any agreement that provides, or will provide, a benefit to the recipient whether in the form of salary, wages, commissions, fees, stock options, interest, bonuses or otherwise.
G. Individual Criminal History and Civil Litigation: For all individuals listed in the organizational chart, investors, or individuals with compensation agreements with the applicant, provide a list of any criminal history and civil litigation (as a plaintiff or defendant) for all individuals.
H. Manufacturer Indebtedness Information: Describe the nature, type, terms, covenants, and priorities of all outstanding bonds, loans, mortgages, trust deeds, pledges, lines of credit, notes, debentures, or other forms of indebtedness issued or executed, or to be issued or executed, in connection with the opening or operating of the manufacturing facility.
I. Financial Statements: Provide the following for the applicant business:
    1. Audited financial statements for the previous three (3) years, which shall include, but not be limited to, an income statement, balance sheet, statement of retained earnings or owner equity, statement of cash flows, and all notes to such statements and related financial schedules, prepared in accordance with generally accepted accounting principles, along with the accompanying independent auditor's report.
        a. If the audited financial statements are more than three months old, provide an affidavit indicating that there are no material changes subsequent to the most recently submitted financial statements.
        b. If the applicant was formed within the year preceding this application, provide certified financial statements for the period of time the applicant has been in existence and any pro forma financials used for business planning purposes.
J. Disclosure of Litigation: The applicant shall disclose any pending or threatened litigation, administrative, or regulatory proceedings or similar matters which could affect the ability of the applicant to perform the required services.
    1. Failure to disclose such matters at the time of application may result in rejection of the application or in termination of any subsequent contract. This is a continuing disclosure requirement. Any such matter commencing after submission of an application must be disclosed within 30 days in a written statement to the Department.
K. Disclosure of Contract Default: Indicate whether the applicant or subcontractor has ever defaulted on a contract, include:
    1. Name of Contract or subcontract
    2. Contact person's telephone number and email address
    3. A brief description of the incident
L. Disclosure of Terminated Contract: Indicate whether the applicant or subcontractor has ever terminated a contract, include:
    1. Name of Contract or subcontract
    2. Contact person's telephone number and email address

3. A brief description of the incident

M. Disclosure of Financial Accountability: Disclose each irregularity (as applicable) of accounts maintained by the applicant discovered by the applicant's accounting firm, the applicant, or any other third party. Failure to disclose such matters, including the circumstances and disposition of the irregularities at the time of application may result in rejection of the application or in termination of any subsequent contract. This is a continuing disclosure requirement. Any matter commencing after submission of an application must be disclosed within 30 days in a written statement to the Department.

N. Disclosure of Financial Accountability Contact Information: Provide the name and contact information for the person the Department can contact regarding financial irregularities.

2. Manufacturing Facility

A. Specify the physical location of the proposed manufacturing facility.

B. Location Authorization: Provide documentation sufficient to establish that the applicant is authorized to conduct business in the State of Iowa; and that state and local building, fire, and zoning requirements and all applicable local ordinances are or will be met for the proposed location of the manufacturing facility.

C. Location Support/Dissent: Provide documentation of any support or dissent by a local government authority for the proposed manufacturing facility location.

D. Hiring/Background Checks: Describe how the manufacturer will vet potential employees to ensure that all employees are at least 18 years old and have not been convicted of a disqualifying felony offense. Describe how the manufacturing licensee will inform the Department of potential new hires to initiate the required background investigation and national criminal history background checks.

E. Ownership: Provide documentation that the proposed manufacturing facility location is owned by the applicant. If not owned by the applicant, provide a written statement from the property owner certifying that the property owner has consented to the applicant operating a manufacturing facility at that location and the duration of the actual or planned lease.

F. Displayed Graphics: Describe signage, lettering, text and graphic materials that will be shown on the exterior of the manufacturing facility.

G. Site Plan: Provide a site plan, drawn to scale, of the proposed manufacturing facility showing perimeter fencing as well as all streets, property lines, buildings, parking areas, and outdoor areas, if applicable, that are within a 500-foot radius of the manufacturing facility.

H. Site Blueprint: Provide a blueprint or floor plan, drawn to scale, of the proposed manufacturing facility, which shows and identifies the following information:

1. The square footage of the overall manufacturing facility.
2. The locations and square footage of all areas that may contain cannabis (plants and plant material, waste, extracts, etc.) or medical cannabidiol with descriptions of the activities to occur in the spaces. The diagram should include walls, partitions, and all areas of ingress and egress. Said diagram must also reflect all cultivation, propagation, harvest, extraction, refinement, testing, storage, packaging and labeling, and transportation areas.

3. The square footage and location of areas to be used as storerooms or stockrooms, if not included above.
4. The location of pesticide, fungicide, and fertilizer storage, mixing, and cleanup areas, including equipment storage and cleanup.
5. The location of all break rooms, employee lockers, and employee shower facilities (for those applying pesticides or other crop inputs).
6. The locations of any business operations on the property that will not be related to the production and distribution of medical cannabidiol.

I. All points of entrance and exit at the manufacturing facility.
J. Construction Plan: Provide a site development and construction (or conversion) plan identifying the construction start date, duration, and completion date.
K. Describe any air treatment system or other means to reduce odors released from the facility.
L. Explain previous experience with developing secure and/or regulated manufacturing facilities.

3. Security Requirements

A. Provide a plan to meet the restricted access requirements of 641 IAC 154.18(1) to 154.18(2).
B. Provide a plan to meet the perimeter intrusion detection system requirement of 641 IAC 154.18(3), including a floor plan noting the location of all cameras. Describe the storage capabilities for the onsite retention of historical recordings. Note that network cameras do not meet the definition of a closed-circuit TV system, but they may be used in addition to closed-circuit TV systems.
C. Provide a plan to meet the security alarm system requirements of 641 IAC 154.18(4).
D. Provide a plan to meet the personnel identification system requirements of 641 IAC 154.18(5).
E. Security Contractors: Provide the names and addresses of any contractors that will be hired/potentially hired to provide security.

4. Personnel Background and Training

A. Staffing:
    1. Provide a proposed staffing chart when the licensed manufacturing facility is at full capacity.
    2. Provide position descriptions that include descriptions of required qualifications and technical expertise for each position. Describe how the business will recruit qualified employees.
    3. Describe the desired qualifications of and the number of employees to be involved in extraction, refinement, and production of medical cannabidiol.
B. Resumes: Provide the resume and experience of any staff that have been hired/retained to fill positions on the proposed staffing chart. Indicate the position each staff member will fill.
C. Consultants: Provide a list of consultants that will be used for education and training of employees, if applicable.
D. Employee Security and Safety Training: Describe how the business will train employees on security and safety.

E. Employee Policy and Regulation Training: Describe how the business will train employees on company policies, administrative rules, and applicable laws.

5. Cultivation

A. Applicant Experience
   1. Describe the applicant's experience designing, building and operating controlled growth environments. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.
   2. Describe the applicant's experience growing cannabis or other agricultural/horticultural crops.

B. Cultivation Plan - Facility Diagram
   1. Provide a labeled diagram of all areas of the proposed facility where cultivation activities will take place, including:
      i. Propagation
      ii. Transplanting
      iii. Vegetative plant growth
      iv. Flowering plant growth
      v. Post-harvest processing and storage
      vi. Waste/Compost processing and storage
      vii. Water/Irrigation layout
      viii. Fertilizer and other crop input mixing areas
      ix. Crop input storage, including fertilizer and soil or soilless media.

C. Cultivation Plan - Operations and Management
   1. Controlled Environments: Describe the controlled growth environments, systems, and automation that will be used to cultivate *Cannabis* from seed or cutting to harvest.
   2. Crop Inputs:
      i. Indicate the growing media that will be used to grow plants from cutting to harvest.
      ii. Indicate what crop inputs will likely be used from propagation to harvest of *Cannabis* plants, and describe how these will be applied and recorded, consistent with 641 IAC 154.25(2). Crop inputs include, but are not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments. Note that the Iowa Department of Agriculture and Land Stewardship (IDALS) has not approved any pesticides for use on *Cannabis*. See Iowa Code chapter 206 and 21 IAC chapters 44 and 45 for state law and regulations governing application and use of pesticides. State laws and regulations on the use of fertilizers can be found in Iowa Code chapter 200 and 21 IAC chapter 43 and 44.
      iii. Describe who will be certified to apply pesticides, fungicides, or other insecticidal agents at the manufacturing facility and how the credentials will be reviewed to ensure that all licenses and recertification requirements are met according to Iowa pesticide laws and regulations (Iowa Code chapter 206, and 21 Iowa

Administrative Code chapters 44 and 45) as well as FDA and EPA regulations.

iv. Describe biosecurity measures to minimize contamination consistent with 641 IAC 154.25(1).

v. Describe the protocol to be used if a fungal or pest outbreak were to occur to both address the issue and resume/restart cultivation.

3. Harvest: Describe the harvest and post-harvest procedures that will be used to prepare plant material for extraction.

D. Waste

1. Describe the processes for disposing of any medical cannabidiol waste generated during the cultivation and harvest of cannabis plants at the manufacturing facility in accordance with 154.23(2).
2. Describe the processes for disposing of any hazardous waste generated during the cultivation of cannabis plants at the manufacturing facility in accordance with 641 IAC 154.23(4). Include the disposal procedure of any mercury, heavy metal, or halogen-containing lights, if applicable.

6. Extraction

A. Applicant Experience

1. Describe the applicant's experience related to cannabis extraction. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.

B. Extraction Plan: Facility Diagram

1. Provide a labeled diagram of the areas of the proposed facility where all cannabis extraction activities will take place, including:
   i. The location of extraction and refinement equipment.
   ii. Storage areas of all cannabis and cannabis extracts.

C. Extraction Plan: Operations and Management

1. Extraction Methods: Describe the method(s) that will be employed to extract the active ingredients from the *Cannabis* plant to produce cannabis extracts and concentrates. Include a description of the equipment that will be used in extraction and refinement.
2. Solvents: Indicate any solvents that will be used in the extraction and refinement of cannabis.
   i. Describe the process for disclosing solvents to the Department pursuant to 641 IAC 154.24(4)*c.*
3. Describe the processes used to ensure the safe removal of any processing solvents from cannabis extracts, if applicable.
4. Describe how cannabis extracts will be stored.

D. Waste:

1. Describe the processes for disposing of medical cannabidiol waste and plant material waste generated during cannabis extraction and refinement in accordance with 154.23(2).
2. Indicate any hazardous material waste that will be generated during

the extraction and refinement of cannabis, and describe the processes for disposing of the waste in accordance with 641 IAC 154.23(4).

7. Medical Cannabidiol Product Formulation & Manufacturing

A. Applicant Experience
   a. Describe the applicant's experience related to formulating medical cannabidiol products from cannabis extracts. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.

B. Product Formulation and Packaging Facility Diagram
   a. Provide a labeled diagram of all areas of the proposed facility where all medical cannabidiol products will be formulated from cannabis extracts, including:
      i. The location of equipment used to formulate medical cannabidiol products.
      ii. Secure storage areas of all in-process medical cannabidiol and finished medical cannabidiol products.
      iii. Storage areas of any product ingredients.

C. Proposed Products Plan
   a. Describe the medical cannabidiol products that will be produced at the licensed manufacturing facility. Product forms are limited to those indicated in 641 IAC 154.14 as amended by ARC5082c.

D. Product Formulation & Manufacturing Plan
   a. Describe all additives, excipients, flavorings, or other products that will be used in producing medical cannabidiol.
   b. Describe procedures for ensuring that the cannabinoid content of manufactured medical cannabidiol products will be homogenous.
   c. Describe how all general sanitation requirements in 641 IAC 154.25(4) will be met.

E. Product Packaging and Labeling Plan
   a. Describe procedures for packaging and labeling final medical cannabidiol products in compliance with 641 IAC 154.21.

8. Quality Assurance and Control

A. Describe the elements of the quality control program, consistent with 641 IAC 154.26, including the qualifications of staff involved in sampling, laboratory testing, and determining product purity and stability. Include the experience and credentials of any person employed by the applicant who has expertise in laboratory testing and stability testing, including the person's name and position.

B. Describe any onsite testing equipment that will be used to perform internal QA prior to transferring samples of concentrate (pesticides, metals, solvents) or finished products (microbiological impurities, potency) to a laboratory.

C. Sampling: Describe medical cannabidiol sampling procedures consistent with 641 IAC 154.26(2), including:
   1. Sampling protocols;
   2. Documentation;
   3. Labeling; and

4. Retention of results.

D. Describe the testing procedures consistent with 641 IAC 154.26(3) and 154.72, including expected frequency and volume of testing; the type of testing that will be requested; protocols for samples that fail to meet acceptance criteria; and procedures for documenting test results, assessments, and destruction of failed product lots.
E. Describe how the stability testing procedures detailed in 641 IAC 154.26(4) will be met. Include a description of:
    1. Procedures for stability testing of each product type and determination of storage conditions;
    2. Plans to involve dispensaries in shelf-life and product expiration date studies;
    3. Intervals for testing; and
    4. Timeline for the development of the stability testing program.
F. Describe the procedures for reserving samples from each lot consistent with 641 IAC 154.26(5).
G. Describe the procedures for disposal of substandard medical cannabidiol products consistent with 641 IAC 154.26(7).
H. Describe the process to collect, review, analyze and determine actions needed when information on adverse events from patients using the medical cannabidiol is discovered.
I. Iowa Code Chapter 124E does not allow manufacturers to have access to patient and primary caregiver information. Given this limitation, describe recall and market withdrawal procedures consistent with 641 IAC 154.26(8). Include a description of:
    1. The factors that would make a recall or market withdrawal necessary;
    2. The personnel who would be responsible for overseeing the recall or market withdrawal; and
    3. How the manufacturer will work with the Department to notify affected parties, including a projected timeline for the process.

9. Packaging and Labeling

A. Describe planned medical cannabidiol packaging consistent with 641 IAC 154.21(1).
B. Describe the intended medical cannabidiol trade names consistent with 641 IAC 154.21(2).
C. Describe medical cannabidiol package labeling consistent with 641 IAC 154.21(3), including a sample label template for each type of product proposed. A space no smaller than 0.75 inches wide by 0.5 inches high should be reserved on the label for the Department's universal symbol for THC.

10. Transportation

A. Describe any experience in transporting products of high value with potential risk for diversion.
B. Describe how medical cannabidiol will be transported to and from dispensaries and the laboratory consistent with 641 IAC 154.22 and proposed administrative rule 154.71(2). Include the following in the narrative:

1. The frequency of medical cannabidiol transport to each location;
2. The frequency of collection of waste medical cannabidiol from dispensaries and the laboratory consistent with 641 IAC 154.23(1);
3. Proposed methods for minimizing the risk of diversion or theft of medical cannabidiol during transport; and
4. Describe the vehicle that will be used for the transportation of medical cannabidiol.

11. Disposal

A. Describe the process for collecting and documenting medical cannabidiol that has been returned from patients and dispensaries as detailed in 641 IAC 154.23(1).
B. Describe how medical cannabidiol and plant material waste will be stored and disposed of consistent with 641 IAC 154.23(2). Include estimates of the amount of waste products that will need to be stored and disposed of. Describe the waste disposal site or sites (these are not licensed by the Department).
C. Describe the process for disposal of liquid and chemical waste consistent with 641 IAC 154.23(3). Include estimates of the amount of liquid and chemical waste that will need to be disposed of and the location of the waste facility.

12. Record-keeping Requirements

Manufacturing licensees are required to input inventory and sales data into the Department's Secure Sales and Inventory Tracking System via an Application Programming Interface (API). The details for integrating with the Department's system are referenced in the IDPH Integration MFG API guide V.6.0 and State API Validation Process v.1.0, which are included as an attachments in Section 5 - Attachments. The applicant must complete multiple sections and include the following:

A. Manufacturing Software Section: Indicate the software that will be used to manage manufacturing inventory for cultivation, extraction, product formulation, finished products, testing, and transfers to and from a laboratory and dispensaries. Describe the applicant's experience using the software in a regulated cannabis program.
B. Technical Specification Section: Describe the technical specifications around the manufacturing software's API capabilities and technology stack.
C. Integration Section: Describe the plans for integrating the manufacturing software with the Department's Secure Sales and Inventory Tracking System, including: required customization, testing, ongoing technical support, and Service Level Agreements (SLAs). Describe the plans for validating that the selected manufacturing software passes all of the required test cases as outlined in the IDPH Manufacturing API Validation Process v.1.0 document, which is provided in Section 5 - Attachments.
D. Record-Keeping Requirements Section: In the narrative field, describe how the record-keeping requirements in administrative rule 154.24 will be met, including how and where each type of record will be stored.

13. Supply and Inventory

A. Describe the procedures for ensuring a reliable and ongoing supply of medical cannabidiol to the dispensaries consistent with 641 IAC 154.27.
B. Describe the Inventory controls and procedures that will be used to prevent and detect diversion, theft, or loss in a timely manner consistent with 641 IAC

154.27(2), include:

1. The process for any employee to report the suspected or confirmed diversion of *Cannabis* plants, medical cannabidiol or medical cannabidiol waste;
2. Record-keeping systems for maintaining a real-time record of the inventory of plant material and medical cannabidiol;
3. The personnel roles/duties used to maintain inventory control;
4. The scope and schedule for periodic physical inventory count.

C. Describe the procedures for inventory of medical cannabidiol waste and plant material waste consistent with 641 IAC 154.27(4), including the personnel, record-keeping, and schedule of the physical inventory counts.
D. Describe procedures for inventory reconciliation consistent with 641 IAC 154.27(5), including the personnel involved and the schedule for the inventory reconciliation.

14. Business Overview and Plan

A. Provide an analysis of the strengths, weaknesses, opportunities, and threats associated with the proposed business and explain how the applicant intends for the business to become successful.
B. Has a market analysis been completed for the business? If yes, provide.
C. Describe the steps and anticipated timeframes for becoming operational as a manufacturer and having medical cannabidiol available at dispensaries by July 1, 2021, including but not limited to: onset of cultivation, date of first harvest, onset of extraction and product formulation, delivery of samples to a laboratory, delivery of final products to dispensaries.
D. Describe the proposed production capacity by July 1, 2021, and in the second and third year of operation. Include a description of the ability to expand capacity to meet future demand. Production capacity includes cultivation, extraction, and final product production.
E. Outline the anticipated product release dates of the proposed products indicated in #7, Medical Cannabidiol Product Formulation & Manufacturing.
F. Describe how the business will set pricing, initially and thereafter, based on supply and demand.
G. Describe the estimated monthly revenues and expenses for the business in the first 2 years of operation, including factoring in testing costs as provided in Section 5 - Attachments. What are the estimates based on?
H. Describe the financial plan for the business. Specifically address financing if FDIC banks and NCUA insured credit unions do not provide loans or financing to the legal cannabis industry and how you will complete financial transactions.
I. Give a summary of the business continuity plan should there be a loss of power or other natural or man-made event that precludes manufacturing at the site for a period of time, keeping in mind that manufacturers are limited to a single physical location.
J. Describe how the business will contribute to maintaining competitiveness in Iowa’s medical cannabidiol program.
K. Describe how the dispensary business will contribute to social equity within Iowa’s medical cannabidiol program.

15. Advertising and Marketing

A. Describe planned marketing and advertising activities consistent with 641 IAC 154.20(1), including templates for manufacturer displays, signs, website pages, and educational materials.
B. Describe other marketing and advertising activities consistent with 641 IAC 154.20(2) intended to be conducted in the first year.
C. Describe how interior displays of medical cannabidiol, signs and other exhibits will be arranged to prevent viewing from outside the manufacturing facility consistent with 641 IAC 154.20(3).

16. Operating Documents

Attach a copy of each of the following operating documents, consistent with 641 IAC 154.17(1). Applicants must include procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

A. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;
B. The methods of planting, harvesting, drying, and storing *cannabis*;
C. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;
D. The disposal methods for all waste materials;
E. Employee training methods for the specific phases of production and who (or what position) will be responsible for oversight of the training;
F. Biosecurity measures used in the production and manufacturing of medical cannabidiol;
G. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;
H. Sampling strategy and quality testing for labeling purposes and product expiration date determination;
I. Medical cannabidiol packaging and labeling procedures;
J. Procedures for mandatory (i.e., recall) and voluntary (i.e., market withdrawal) of medical cannabidiol;
K. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;
L. A business continuity plan;
M. Records relating to all transport activities;
N. Handling, storage, application, and disposal of pesticides, fertilizers, and other crop inputs;
O. Oversight of all personnel and phases of manufacturing and production of cannabidiol (including a table of organization);
P. Procedures to ensure accurate recordkeeping; and
Q. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol.

SECTION 4 – APPLICATION REVIEW PROCESS AND CRITERIA

4.01 Overview of Review Process

Review and evaluation of applications submitted under this RFP will be conducted in three phases.

A. Phase I – Technical Review
The first phase will involve a preliminary review by Department staff of an applicant's compliance with the mandatory requirements to include but not limited to: eligibility requirements to include but not limited to: letter of intent submitted by deadline, registration with Iowa SOS, disclosure of owners, proper zoning form, and application fee check; as well as complete certification forms, and application content for submitted applications. Applications which fail to satisfy technical requirements or application content or fail to submit the application fee by the deadline may be eliminated from the application review. These applications may be rejected. The Department will notify the applicant of a rejection that occurs during Phase I of the review process. The Department reserves the right to waive minor variances at the sole discretion of the Department.

B. Phase II – Review Committee
Applications determined to be compliant with technical and mandatory requirements in Phase 1 will be accepted for the second phase of evaluation, which shall be completed by a review committee established by the Department. The membership of the review committee shall be determined by the bureau chief with input and oversight from the respective division director.

The review committee shall evaluate applications and score in accordance with a point system. Each committee member will review the applications and the evaluation criteria outlined in this chapter and assign a point total for each criterion.

The Department reserves the right to solicit information from subject matter experts who may provide information to the review committee members about particular components of the RFP, the manufacturing requirements, and/or the applications received.

If an applicant is requested to make an oral presentation of the application pursuant to Section 1.13, the committee members may consider the oral presentation of the applicant in determining the points awarded.

The total score awarded by each committee member will be averaged to arrive at the final score for each application, and the applications will then be ranked based on the average of the evaluation scores. The Department staff may solicit additional input and recommendations from the review committee.

In the event applications receive an equal number of points (tie score), the applications will be ranked accordingly and the award process will continue with

Phase III.

C. Phase III – Department Review and Award
The third phase will be a final review. The Department will consider the submitted applications and the review committee's score and recommendations.

The Department may also consider geographical location, financial solvency of applicant, any owner's historical noncompliance with licenses held elsewhere, any information received pursuant to Section 1.16 - 1.22 of the RFP, and any other information received during the award process. The Department reserves the right not to award a license to the applicant with the highest average score.

4.02 Scoring of Applications

A maximum of 1,000 points may be awarded to each application. A minimum score of 600 points or greater is required for the application to be considered for award of a license. Applications scoring less than the minimum score will be rejected. Accepted applications will be evaluated based on the following criteria:

A. All parts of each section are included and addressed.

B. Descriptions and detail are clear, organized, and understandable.

C. Descriptions are responsive to the intent of the RFP objectives.

D. The overall ability of the applicant, as judged by the review committee, to successfully meet the RFP, administrative rules, and statutory requirements within the proposed schedule.

Points will be assigned for each item listed as follows:

5 Applicant's application or capability is exceptional and exceeds expectations for this criterion.

4 Applicant's application or capability is superior and slightly exceeds expectations for this criterion.

3 Applicant's application or capability is satisfactory and meets expectations for this criterion.

2 Applicant's application or capability is unsatisfactory and contains numerous deficiencies for this criterion.

1 Applicant's application or capability is not acceptable or applicable for this criterion.

The maximum points to be awarded for each application section are as follows:

Application Form	Weight	Potential Maximum Score
Medical Cannabidiol Manufacturer Application Certification and Conditions Form	Required Form	N/A
Statutory Requirements Certification Form	Required Form	N/A
Licensing/ Regulatory Authority Release Form	Required Form	N/A
Proper Zoning Form	Required Form	N/A
Owner Certification Form	Required Form	N/A
1. Business Organization, Ownership, and Financial Structure	10	50
2. Manufacturing Facility	15	75
3. Security Requirements	10	50
4. Personnel Background and Training	10	50
5. Cultivation	15	75
6. Extraction	15	75
7. Medical Cannabidiol Product Formulation & Manufacturing	20	100
8. Quality Assurance and Control	20	100
9. Packaging and Labeling	5	25
10. Transportation	5	25
11. Disposal	5	25
12. Record-Keeping Requirements	20	100
13. Supply and Inventory	5	25
14. Business Overview and Plan	25	125
15. Advertising and Marketing	5	25
16. Operating Documents	15	75
Total Maximum Points:		**1000**

SECTION 5 – ATTACHMENTS

These forms are posted as separate files on the Department website under Funding Opportunities:

- A - RFP #58821019 to License Medical Cannabidiol Manufacturers
- B - Draft RFP #58821019 License Medical Cannabidiol Manufacturers Score Tool
- C - Iowa Medical Cannabidiol Program Market Analysis
- D - HF2589 Summary Document
- E - v6.0 IDPH Integration Manufacturing API guide
- F - v1.0 IDPH Manufacturing API Validation Process
- G - v4.3 Laboratory Testing & Acceptance Criteria Document
- H - v1.0 IDPH Product Testing Verification & Validation Study Form
- I - IDPH Medical Cannabidiol Testing Process Flowchart
- J - SHL Product Testing Cost Sheet
- K - Form 22 for Redacted Applications

SECTION 6 – LINKS

The following reference documents are available by clicking on the link provided in the website Links section of this Funding Opportunity:

- Medical Cannabidiol Act (Iowa Code chapter 124E)
- House File 2589
- ARC5082c (amendments to 641 IAC 154 based on HF2589)
- 641 Iowa Administrative Code (IAC) chapter 154
- 21 Iowa Administrative Code chapter 43 – Fertilizers and Agricultural Lime
- 21 Iowa Administrative Code chapter 44 – On-site Containment of Pesticides, Fertilizers, and Soil Conditioners
- Iowa Code chapter 200 – Fertilizers and Soil Conditioners
- 21 Iowa Administrative Code chapter 45 – Pesticides
- Iowa Code chapter 206 – Pesticides